

Interview Summary and Remarks

The courtesy of the Examiner in granting a telephonic interview to the undersigned on June 24, 2008 is appreciated. The following recordation of the substance of the interview is believed to be complete and proper, in accordance with MPEP 713.04. It is requested that the Examiner notify the undersigned if she believes this Summary contains any inaccuracies or if she believes it is otherwise not complete and proper. The pending claims were discussed during the interview, together with the various items mentioned below. No agreement was reached.

This communication responds to the Office Action mailed December 28, 2007, for the application captioned above, the period for response to which is extended to June 28, 2008 with the accompanying Petition for Extension of Time.

Claims 6, 14-26 and 29-33 are pending in the application. Claims 1-28 and 30-33 have been cancelled without prejudice, and new claims 34-74 have been added. Upon entry of the present amendment, claims 29 and 34-74 will be pending and in condition for allowance.

Antecedent basis for the various amendments can be found throughout the specification, for instance, at page 4, lines 10-15 (autologous); page 7, lines 13-17 (perioperative); page 8, lines 18-24 and page 12, lines 23-30 (cell types and ratios); and page 5, lines 1-5 (distribution to a graft site).

The objection to claim 33 has been rendered moot by virtue of the cancellation of that claim without prejudice.

With regard to the rejection under Section 112, second paragraph, Applicants assert that the terms “xenogenic” and “autologous” will be amply clear to those skilled in the art, given the present description. Hopefully, the claims as now provided are suitable to render moot the concern regarding the relationship between the tissue donor and the recipient of the suspension.

The remaining rejections regarding claims 14, 32 and 33 have been rendered moot by the cancellation of these claims without prejudice.

As discussed with the Examiner, none of the cited references describe or achieve Applicant's product as presently claimed. The claims have been amended in order to facilitate the prosecution of the present application, by focusing the claims on the suspension as it exists upon the graft site. In turn, many of the related features become all the more remarkable and meaningful, while the stark differences between the present invention and each of the references becomes all the more apparent.

If provided the patentable weight they deserve, various aspects of the independent and dependent claims can be readily seen as lacking in the various prior art. These aspects include, for instance, the preparation or use of a cell suspension, in a perioperative fashion, for use as an autologous tissue (e.g., skin) graft, having a composition of viable cells that is similar to the donor site, or distributed in the form of a spray, etc.

Several of the references do not appear to be concerned with the preparation or use of an autologous tissue graft at all, let alone one providing the various other features as presently claimed. See, for instance, Suzuki (provides a medium and process for cultivating cardiac cells), Noel-Hudson (studies cell differentiation by culturing cells to form a synthetic membrane), Lucas (isolates a myogenic protein from bone); Dennis (creates a muscle construct using anchors applied to a substrate); Lavker (culturing hair follicular stem cells); and Hirobe (studies the relationship between various cell types and factors in the course of cell differentiation) .

To the extent any of the cited references do address such things as tissue or corresponding grafts, they approach the matter from very different perspectives, and in turn, each have one or more key differences from the suspension and process of the present invention.

Yannas, for instance, takes cells that have been expanded in culture, and centrifuges them onto a fibrous lattice that is then applied to the skin. It is not clear what the composition of cells may be, or if they are viable, and by forming a bed of centrifuged cells the authors seem quite

unconcerned about the presence of cell conglomerates. Certainly Yannas does not apply a cell suspension to a graft site in the manner presently claimed.

Similarly, Osborne provides an artificial skin substitute having cells on a collagen based substrate, and focuses far more on aspects of the substrate than the cells themselves. In addition to what would appear to be its many other differences, it is certainly clear that Osborne also does not apply a cell suspension to a tissue site in the manner presently claimed.

Finally, Katz is even further removed, in that it focuses largely on what it considers to be a unique device for dissociating tissue. The document neither teaches nor suggests the preparation or use of a cell suspension in the manner presently claimed, and instead seems to essentially end at the point of collecting a cell suspension for further processing in a “centrifuge ready receptacle” presumably still containing both proteolytic enzyme and “unwanted debris” (col. 7, lines 43).

Hence, it can be seen that the present claims, properly and fully considered, provide a number of distinctions over each of the cited references. Reconsideration of the rejections and allowance of all pending claims at an early date is respectfully requested. The Commissioner is hereby authorized to charge any additional fees required to Deposit Account No. 061910.

Respectfully submitted,

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